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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,714	08/09/2006	Kristine Debruyne	62367-393343	4670

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KILPATRICK STOCKTON LLP
1100 Peachtree Street
Suite 2800
ATLANTA, GA 30309

EXAMINER	
KAHELIN, MICHAEL WILLIAM	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
12/30/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipefiling@kilpatrickstockton.com
jlhice@kilpatrick.foundationip.com

Office Action Summary	Application No.	Applicant(s)	
	10/536,714	DEBRUYNE ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54,56-75,77-81 and 83-85* is/are pending in the application.

4a) Of the above claim(s) *54 and 56-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-75,77-81 and 83-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20101130*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 54 and 56-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/1/2010.

2. Applicant's election without traverse of claims 70-75, 77-81, and 83-85 in the reply filed on 11/1/2010 is acknowledged.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 84 and 85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In regards to claim 84, the examiner was unable to find written description support in the originally-filed disclosure for a collar having a "non-porous cavity" (the disclosure appears to be silent as to the porosity of the cavity) or an outlet that "faces the electrode assembly" (the outlet appears to face distally in all embodiments). In regards to claim 85, while the examiner was able to find support for a semi-permeable membrane that can act as a valve means (page 32 of the

original disclosure), the examiner was unable to find support for an outlet comprising a valve. Apparently, the scope of "a valve" would include actual mechanical valve elements (like flap valves), but the disclosure only appears to support a semi-permeable membrane that "can act as a valve means." Other embodiments do not appear to be supported.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim element "a slider means for delivery of a bioactive substance" is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. The phrase "slider means" appears to be absent from the original disclosure, and the disclosure also appears to lack any guidance as to precisely which structure or structures constitute the "slider means." Applicant's "Remarks" of 8/6/2010 appear to indicate that the "slider means" corresponds to the collar of Figure 19, but do not indicate which of the features from this figure are necessarily part of the "means." For instance, Applicant notes that Kramm's system "in not the same" as that collar depicted in Figure 19, but does not indicate which structural features or elements that a "slider means" requires, but are lacking in Kramm. This appears to be an "omnibus-type" claim (*i.e.*, "a collar essentially as depicted in Figure 19") without an explanation or indication of what the essential

features are. The claim is indefinite in that it fails to point out what is included or excluded by the claim language.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 70, 72-75, 78-81, and 83 are rejected under 35 U.S.C. 102(e) as being anticipated by Kramm et al. (US 6,936,040, hereinafter "Kramm").

8. In regards to claim 70, Kramm discloses an electrode assembly comprising a lead extending from the stimulator unit, and a contiguous elongate member implantable in the tortuous coronary vasculature (col. 2, lines 57-65); one or more electrodes disposed on or in the elongate member each configured to deliver electrical stimulation

to the cochlea (or any other location in the body; col. 5, lines 6-16); and a slider means for delivery of a bioactive substance mounted around the lead such that the lead extends through a lumen in the collar (Fig. 6; element 48, 42, and 56), the collar having a chamber therein (56) configured to receive a biactive substance (col. 6, lines 45-50) and deliver the bioactive substance to a target in the recipient. The examiner is considering Kramm's element 48 and distal portions of 42 and 56 to be equivalent to the claimed "slider means" because it slides with respect to the lead and functions to deliver bioactive substances to a target site in a recipient. Applicant has not indicated that any further structure is required.

9. In regards to claim 73, Kramm discloses that the slider means has a plurality of different diameters along its length (Fig. 6).

10. In regards to claim 74, the slider means comprises a chamber (56), and the resistance to flow provided by the semi-permeable distribution device (48) necessarily retains the bioactive substance in the chamber for some arbitrary period of time (col. 6, lines 45-50).

11. In regards to claim 75, the chamber is annular and surrounds the lumen of the slider means through which the electrical lead passes (Fig. 6 -- for the purposes of this claim, the interstices of element 48 is considered part of the "chamber" because it too is an "enclosed space", enclosed by the outer boundary of element 48).

12. In regards to claims 78-81, the collar comprises an inlet in fluid communication with the chamber (proximal end of 56); the chamber (56) being configured to pass the bioactive substance from the inlet to outlet (Fig. 6 -- the outlet being either the very

distal point of element 56 or the surface of element 48); and wherein the chamber is a pipe extending through the collar from the inlet to outlet (Fig. 6).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 72 and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramm in view of Kuzma (US 6,309,410, hereinafter "Kuzma").

16. In regards to claims 72, 83, and 84, Kramm discloses the essential features of the claimed invention including that the lead is dimensioned to be implantable in the small, tortuous coronary vasculature (col. 5, line 47); and an annular collar (elements 42, 48, and 56) mounted on the lead and having a non-porous cavity (lumen of 56) therein and an outlet located on an exterior face of the collar through which the

bioactive substance can pass (48), wherein the outlet faces the electrode assembly (the inner and distal surfaces of 48 face the electrode assembly in a radially-inward direction and in a distal direction) and forms a boundary of the cavity (the distal boundary at the distal end of 56's lumen -- see Fig. 6). Kramm does not explicitly disclose that the lead is implantable in a cochlea/middle ear, the collar dimensioned to slide along the lead in the middle ear, or that the system is a cochlear implant. However, Kuzma discloses a similar cochlear drug delivery/electrical stimulation system implantable in a cochlea middle ear, the drug delivery device dimensioned to slide along the lead in the middle ear (Figs. 2a and 2b) to provide the predictable results of providing known therapeutic auditory stimulation while providing known pharmacological benefits such as preventing fibrosis or promoting neural growth (col. 3, lines 40-49). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kramm's device by providing a cochlear drug delivery/electrical stimulation system implantable in a cochlea middle ear, and the collar dimensioned to slide along the lead in the middle ear to provide the predictable results of therapeutic auditory stimulation while providing known pharmacological benefits such as preventing fibrosis or promoting neural growth.

17. In regards to claim 85, the examiner is considering Kramm's semi-permeable distributor as necessarily capable of providing the claimed functional limitations due to the pressure differential required to deliver a bioactive substance (*i.e.*, to deliver the substance, the substance necessarily needs to be flowing out and substantially preventing fluid from flowing in). At least at the time of delivery of the substance,

Kramm meets these limitations. Further, Applicant's disclosure indicates that a semi-permeable membrane is within the scope of a "valve" (see §112 rejections above).

18. In regards to claims 71 and 77, Kramm discloses the essential features of the claimed invention except for a "stop" on the lead that prevents the substance delivery means from moving past the stop means; or an outlet that includes a semi-permeable membrane. However, Applicant admitted prior art teaches that it is well known in the cochlear stimulation arts to provide stops on leads that prevent positioning devices, such as Kramm's, from moving past the stop means to provide the predictable result of avoiding damage to the tissue and ensuring proper placement of the electrodes; and to provide drug outlets that include semi-permeable membranes to provide the predictable result of releasing drugs at a specifically desired rate. Therefore, it would have been obvious to one having ordinary skill at the time the invention was made to provide Kramm's invention with a stop on the lead that prevents the positioning device from moving past the stop means to provide the predictable result of avoiding damage to tissue from too deep of insertion and ensuring proper placement of the electrodes; and to provide a drug outlet that includes a semi-permeable membrane to provide the predictable result of releasing drugs at a specifically desired rate.

Response to Arguments

19. Applicant's arguments with respect to claims 70-75, 77-81, and 83-85 have been considered but are moot in view of the new ground(s) of rejection, necessitated by

amendment. Please see the new interpretation of Kramm above in view of the claim amendments.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Primary Examiner, Art Unit 3762